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CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8) Applicant(s): Arnold P. Nerenberg			Docket No. NERE-3692
Application No. 10/625,305	Filing Date 7/23/2003	Examiner Ware, Deborah K.	Group Art Unit 1651

Invention: COMPOSITION FOR MITIGATING A PERNICIOUS THROMBOTIC EVENT

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TRANSMITTAL OF APPEAL BRIEF (Small Entity)	Docket No. NERE-3692

In Re Application Of: Arnold P. Nerenberg

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/625,305	7/23/2003	Ware, Deborah K.	5409	1651	

Invention: COMPOSITION FOR MITIGATING A PERNICIOUS THROMBOTIC EVENT

COMMISSIONER FOR PATENTS:

Transmitted herewith ~~in triplicate~~ is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arnold P. Nerenberg
Filed: 07/23/2003
Serial No.: 10/625,305
Group Art Unit: 1651
Examiner: Ware, Deborah K.
Docket No.: NERE-3692

Title: **COMPOSITION FOR MITIGATING A PERNICIOUS THROMBOTIC EVENT**

Commissioner For Patents
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BRIEF OF APPELLANT

This Appeal Brief, pursuant to the Notice of Appeal filed June 30, 2005, is an appeal from the rejection of the Examiner in the Office Action dated March 31, 2005.

REAL PARTY IN INTEREST

Arnold P. Nerenberg

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Claims 1-31 are rejected. This Appeal Brief is in support of an appeal from the rejection of claims 1-31.

STATUS OF AMENDMENTS

08/31/2005 TL0111 00000031 190513 10625305
01 FC:2402 250.00 DA

There are no After-Final Amendments which have not been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides a composition, comprising: aspirin, magnesium, and nattokinase, and either niacin or nitroglycerine, said composition having a structural form that is suitable for being introduced into a body of a person. The composition is adapted to be introduced into the body of the person for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person. The aspirin, magnesium, nattokinase, and niacin or nitroglycerine may each have a therapeutically effective amount for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person. The pernicious thrombotic event in the person may be a heart attack or stroke in the person. See specification, page 2, lines 12-19.

The structural form of the composition may be a chewable form adapted to being introduced into the mouth of the person. The chewable form may rises a wafer or a chewable tablet. See specification, page 2, line 20 - page 3, line 6.

The structural form of the composition may be a dissolvable form (e.g., in a liquid form) that is adapted to being introduced into the mouth of the person. See specification, page 3, line 7 - page 4, line 1.

The composition of claim 1, wherein the structural form is a spray form, wherein the spray form is adapted to being introduced into the nasal cavity of the person. See specification, page 4, lines 2-7.

The composition of claim 1, wherein the structural form is a suppository form, wherein the suppository form is adapted to being introduced into the anal cavity of the person. See specification, page 4, lines 8-10.

The composition may comprise L-carnitine, alpha lipoic acid, L-arginine, and/or coenzyme Q10. See specification, page 5, lines 8-16.

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, and niacin in a range of 500 to 3000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, niacin in a range of 500 to 3000 mg, and L-carnitine in a range of 2000 to 9000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, niacin in a range of 500 to 3000 mg, L-carnitine in a range of 2000 to 9000 mg, and alpha lipoic acid in a range of 200 to 10000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, niacin in a range of 500 to 3000 mg, L-carnitine in a range of 2000 to 9000 mg, alpha lipoic acid in a range of 200 to 10000 mg, and L-arginine in a range of 2000 to 12000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, niacin in a range of 500 to 3000 mg, L-carnitine in a range of 2000 to 9000 mg, alpha lipoic acid in a range of 200 to 10000 mg, L-arginine in a range of 2000 to 12000 mg, and coenzyme Q10 in a range of 300 to 6000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, and nitroglycerine in a range of 0.4 to 2.5 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, nitroglycerine in a range of 0.4 to 2.5 mg, and L-carnitine in a range of 2000 to 9000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, nitroglycerine in a range of 0.4 to 2.5 mg, L-carnitine in a range of 2000 to 9000 mg, and alpha lipoic acid in a range of 200 to 10000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, nitroglycerine in a range of 0.4 to 2.5 mg, L-carnitine in a range of 2000 to 9000 mg, alpha lipoic acid in a range of 200 to 10000 mg, and L-arginine in a range of 2000 to 12000 mg. See specification, page 6, lines 1-11 (Table 1).

The composition may comprise: aspirin in a range of 650 to 975 mg, magnesium in a range of 300 to 3000 mg, nattokinase in a range of 150 to 3000 mg, nitroglycerine in a range of 0.4 to 2.5 mg, L-carnitine in a range of 2000 to 9000 mg, alpha lipoic acid in a range of 200 to 10000 mg, and L-arginine in a range of 2000 to 12000 mg, and coenzyme Q10 in a range of 300 to 6000 mg. See specification, page 6, lines 1-11 (Table 1).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-31 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cochran in view of Kato et al., McCarty, Riley et al., and Leslie et al.

ARGUMENT

GROUND OF REJECTION 1

Claims 1-31 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cochran in view of Kato et al., McCarty, Riley et al., and Leslie et al., for reasons set forth in the Office Action of October 6, 2004.

Claim 1

Appellant respectfully contends that claim 1 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 1. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "[a] composition, comprising: aspirin, magnesium, and nattokinase, and either niacin or nitroglycerine".

The Examiner cites Cochran as a primary reference for allegedly teaching a composition comprising niacin. The Examiner cites the following secondary references for allegedly teaching a composition comprising other constituents of the composition: Riley (aspirin), McCarty (magnesium), and Kato (nattokinase).

The Examiner argues: "It would have been obvious to one of ordinary skill in the art to combine the ingredients of the cited prior art to provide for a composition since each ingredient is well known in the art. To combine these ingredients of the cited prior art to provide for the composition is an obvious modification and one of skill would have expected successful results."

In response, Appellant respectfully contends that the Examiner has not supplied a legally

persuasive argument as to why a person of ordinary skill in the art would modify Cochran by the alleged teaching of Riley, McCarty, and Kato in relation to claim 1. In particular, established case law requires that the prior art must contain some suggestion or incentive that would have motivated a person of ordinary skill in the art to modify a reference or to combine references. See Karsten Mfg. Corp. V. Cleveland Gulf Co., 242 F.3d 1376, 58 U.S.P.Q.2d 1286, 1293 (Fed. Cir. 2001 ("In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching **in the prior art** that would have led a person of ordinary skill in the art to select the references and combine them in a way that would produce the claimed invention"). See also In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984 ("The mere fact that the prior art could be so modified would not have made the motivation obvious **unless the prior art suggested the desirability of the modification.**"). The Examiner has not made any showing of where the prior art suggests modifying a composition of the type disclosed by Cochran by adding the ingredients of aspirin, magnesium, and nattokinase. By not citing any suggestion or incentive in the prior art for modifying Cochran's composition by adding aspirin, magnesium, and nattokinase, the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 1.

In effect, the Examiner is arguing that it is obvious to combine ingredients merely because the ingredients are known, which has no legal basis. If the Examiner were correct, it would never be possible to at any time in the future to issue a patent having a claim consisting of known features. In fact, a large number of issued patents have claims consisting exclusively of known features, such that the patentablity of these claims are supported only by the novelty and

non-obviousness of the **combination** of the features rather by the features individually. There are hundreds of thousands of such claims in issued patents. Claim 1 of the present invention falls into this category and should be subject to an analysis of whether the combination of features is novel and non-obvious, based on a legally acceptable methodology for performing such an analysis.

Appellant maintains that whether it is obvious to modify Cochran's composition by adding aspirin, magnesium, and nattokinase is impacted by whether the addition of adding aspirin, magnesium, and nattokinase supports the purpose of Cochran's composition. Indeed, Cochran's "composition [is] designed to treat the disease at the molecular/cellular level, focusing strongly on DNA and RNA regulation, RNA template protection, protection of genes and chromosomes, and enhancement of the molecular/cellular language which is spoken and understood by the cells of the body." Appellants note that the Examiner has not provided any evidence demonstrating that aspirin, magnesium, and nattokinase supports "DNA and RNA regulation, RNA template protection, protection of genes and chromosomes, and enhancement of the molecular/cellular language which is spoken and understood by the cells of the body". Therefore, Appellants maintains that the Examiner has not demonstrated that it is obvious to include aspirin, magnesium, and nattokinase in Cochran's composition.

As to aspirin, the Abstract of the Examiner's cited reference of Riley states that "certain modular formulations of the present invention incorporate both antioxidants and acetylsalicylic acid (aspirin) as a single preventive modality. Such a combination of antioxidants and aspirin is believed to act to prevent oxidation of low density lipoproteins within coronary arterial walls and

to cause platelet deagluttination thereby inhibiting thrombus formation. The benefit of preventing these two major processes is believed to reduce the risk of coronary heart disease." Appellants contend that the aforementioned advantages of using aspirin does not make it obvious to add aspirin to Cochran's composition to support or enhance Cochran's stated functionality of "DNA and RNA regulation, RNA template protection, protection of genes and chromosomes, and enhancement of the molecular/cellular language which is spoken and understood by the cells of the body". Therefore, Appellants maintains that the Examiner has not demonstrated that it is obvious to include aspirin in Cochran's composition.

As to nattokinase, the Examiner's cited reference of Kato recites the following advantages of using nattokinase: "to dissolve fibrin in thrombosis" (Kato, col. 1, lines 37-38), ""to put calcium on the human bone by the action of osteocalcin"(Kato, col. 1, lines 42-43), and to "promote digestion of protein foods" (Kato, col. 1, lines 49-38). Appellants contend that the aforementioned advantage of using nattokinase does not make it obvious to add nattokinase to Cochran's composition to support or enhance Cochran's stated functionality of "DNA and RNA regulation, RNA template protection, protection of genes and chromosomes, and enhancement of the molecular/cellular language which is spoken and understood by the cells of the body". Therefore, Appellants maintains that the Examiner has not demonstrated that it is obvious to include nattokinase in Cochran's composition.

Moreover, Cochran teaches away from adding aspirin and nattokinase, since Cochran emphasizes using substances found naturally in the body, and both aspirin and nattokinase are not found naturally in the body. See Cochran, col. 1, lines 10-13: "the invention relates to

various compositions, including, but not limited to, hormones, vitamins, enzymes, amino acids, minerals and other substances **found naturally in the body**" (emphasis added).

In addition, while Appellant acknowledges that nattokinase is known, Appellant traverses the Examiner's contention the nattokinase is well known. There does not exist a large amount of published literature on nattokinase. Appellant contends that Kato discloses nattokinase as an ingredient of Barley Yam Natto derived from a processing of soybean, barley, and yam (see Kato, col. 2, lines 16-24, 48-65). Kato does not teach or suggest that the nattokinase be isolated from the Barley Yam Natto in order to be added to another composition. Nor does Kato teach or suggest that other additives such as aspirin, magnesium, etc. be added to the Barley Yam Natto. Therefore, Appellant contends that it is not obvious from the teaching of Kato to include nattokinase in the composition of claim 1.

In "Response to Arguments", Examiner alleges that "Kato et al clearly teach, or at least suggest, Nattokinase in a composition, note column 3, Table 2, and lines 45-49." In response, Appellant contends that the Examiner's citation is misdirected, because Kato, col. 3, Table 2 merely compares the Barley and Yam Nato of Kato's invention with ordinary Natto on the market and does not teach or suggest the including any additives with nattokinase. Moreover, the Examiner's citation of Kato, col. 3, lines 45-49 does not support the Examiner's contention that Kato teaches or suggests nattokinase in a composition.

Based on the preceding arguments, Appellant respectfully maintains that claim 1 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, and that claim 1 is in condition for allowance.

Since claims 2-31 depend from claim1, Appellant contends that claims 2-31 are likewise in condition for allowance. In addition, dependent claims 2-31 each have an independent basis for not being unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, as discussed *infra*.

Claim 2

Appellant respectfully contends that claim 2 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 2. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the composition is adapted to be introduced into the body of the person for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 2. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 2.

Claims 3 and 5

Appellant respectfully contends that claims 3 and 5 are not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claims 3 and 5. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the

pernicious thrombotic event in the person is a heart attack or stroke in the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claims 3 and 5. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 3 and 5.

Claim 4

Appellant respectfully contends that claim 4 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 4. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the aspirin, magnesium, nattokinase, and niacin or nitroglycerine each have a therapeutically effective amount for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 4. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 4.

Claim 6

Appellant respectfully contends that claim 6 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 6. For example, Cochran in view of

Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the structural form is a chewable form, and wherein the chewable form is adapted to being introduced into the mouth of the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 6. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 6.

Claim 7

Appellant respectfully contends that claim 7 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 7. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: " wherein the chewable form comprises a wafer or a chewable tablet".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 7. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 7.

Claim 8

Appellant respectfully contends that claim 8 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 8. For example, Cochran in view of

Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the structural form is a dissolvable form, and wherein the dissolvable form is adapted to being introduced into the mouth of the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 8. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 8.

Claim 9

Appellant respectfully contends that claim 9 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 9. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the structural form is a liquid form".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 9. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 9.

Claim 10

Appellant respectfully contends that claim 10 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 10. For example, Cochran in view of

Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the structural form is a spray form, and wherein the spray form is adapted to being introduced into the nasal cavity of the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 10. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 10.

Claim 11

Appellant respectfully contends that claim 11 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 11. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the structural form is a suppository form, and wherein the suppository form is adapted to being introduced into the anal cavity of the person".

The Examiner has not presented any argument in support of the Examiner's rejection of claim 11. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 11.

Claims 14 and 24

Appellant respectfully contends that claims 14 and 24 are not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley,

and Leslie does not teach or suggest each and every feature of claims 14 and 24. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "further comprising L-carnitine".

The Examiner has not presented any argument in support of the Examiner's rejection of claims 14 and 24. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 14 and 24.

Claims 18 and 28

Appellant respectfully contends that claims 18 and 28 are not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claims 18 and 28. For example, Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "further comprising L-arginine".

The Examiner has not presented any argument in support of the Examiner's rejection of claims 18 and 28. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 18 and 28.

Claim 22

Appellant respectfully contends that claim 22 is not unpatentable over Cochran in view of Kato, McCarty, Riley, and Leslie, because Cochran in view of Kato, McCarty, Riley, and Leslie does not teach or suggest each and every feature of claim 22. For example, Cochran in view of

Kato, McCarty, Riley, and Leslie does not teach or suggest the feature: "wherein the composition comprises nitroglycerine".

Although the Examiner alleges that Leslie teaches a composition comprising nitroglycerine, the Examiner has not presented any argument in support of the Examiner's contention that it is obvious to modify Cochran's composition to include nitroglycerine. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claim 22.

Claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31

Claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31 each claim a range in units of milligrams for the amount of each ingredient in of the claimed composition.

The Examiner has rejected claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31 by arguing that "[t]o vary the amounts is clearly within the skill of an ordinary artisan." In "Response to Arguments, the Examiner further argues that "[t]he amounts of each ingredient are merely optional and to select for optimum amounts of each ingredient for use together is clearly within the purview of an ordinary artisan. The cited prior art clearly demonstrates that optimum amounts are selected for based on the desired result. The desired result of the combined ingredients of the instant claims is the same as that of the cited prior art."

In response, Appellant cites MPEP 2144.05.II.B which recites that **"Only Result-Effective Variables Can Be Optimized ...** A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the

determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy)."

Thus, based on *In re Antonie* as specifically acknowledged in MPEP 2144.05.II.B, the Examiner must provide evidence that the prior art teaches that the amount of **each specific ingredient** in the composition is a result-effective variable, which the Examiner has not done. Instead of providing evidence directed to each specific ingredient in each composition, the Examiner has instead made a general non-specific statement that "[t]he cited prior art clearly demonstrates that optimum amounts are selected for based on the desired result", which is a broad generalization that fails to address whether **each specific ingredient** in the composition is a result-effective variable." Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31.

Next, Appellant discusses the claimed ranges of nattokinase, aspirin, L-carnitine, and L-arginine in the composition of claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31.

As to nattokinase, each of claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31 recite a range of 150 to 3000 milligrams of nattokinase in the composition. The reference of Kato cited by the Examiner (for adding nattokinase to Cochran's composition) does not suggest that nattokinase should be in a composition (as explained *supra*), does not indicate any range for nattokinase in a composition, and does indicate any range for nattokinase by itself when nattokinase is not in a composition. Moreover the Examiner argues for the obviousness of adding nattokinase to Cochran's composition, and the Examiner has not provided any evidence from the prior art disclosing that the amount of nattokinase is a result-effective variable with respect to the Cochran's composition. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31.

As to aspirin, each of claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31 recite a range of 650 to 975 milligrams of aspirin in the composition. The reference of Riley cited by the Examiner (for adding aspirin to Cochran's composition) teaches an aspirin dose range of 20 to 200 milligrams in the composition (see Riley, col. 5, lines 14-15; col. 18, lines 47-52) which is outside of Appellant's claimed range of 650 to 975 milligrams. Riley also teaches that an optimal aspirin dose range of 20-30 milligrams in the composition (see Riley, col. 5, lines 25-38), which destroys the Examiner's argument of determining an optimal aspirin dosage within Appellant's claimed range of 650 to 975 milligrams. Also, Riley teaches away from the 650 to 975 milligrams of aspirin in the composition claimed by Appellant (see Riley, col. 5, lines 25-

38). In addition, the Examiner argues for the obviousness of adding aspirin to Cochran's composition, and the Examiner has not provided any evidence from the prior art disclosing that the amount of aspirin is a result-effective variable with respect to the Cochran's composition. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 13, 15, 17, 19, 21, 23, 25, 27, 29, and 31.

As to L-carnitine, each of claims 15, 17, 19, 21, 25, 27, 29, and 31 recite a range of 2000 to 9000 milligrams of L-carnitine in the composition. The Examiner has not cited any reference that discloses a range of the amount of L-carnitine claimed by Appellant. The Examiner has not cited any reference that discloses the amount of L-carnitine in the composition to be a result-effective variable. In addition, the Examiner argues for the obviousness of adding L-carnitine to Cochran's composition, and the Examiner has not provided any evidence from the prior art disclosing that the amount of L-carnitine is a result-effective variable with respect to the Cochran's composition. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 15, 17, 19, 21, 25, 27, 29, and 31.

As to L-arginine, each of claims 19, 21, 29, and 31 recite a range of 2000 to 12000 milligrams of L-arginine in the composition. The Examiner has not cited any reference that discloses a range of the amount of L-arginine claimed by Appellant. The Examiner has not cited any reference that discloses the amount of L-arginine in the composition to be a result-effective

variable. In addition, the Examiner argues for the obviousness of adding L-arginine to Cochran's composition, and the Examiner has not provided any evidence from the prior art disclosing that the amount of L-arginine is a result-effective variable with respect to the Cochran's composition. Accordingly, Appellant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness in relation to claims 19, 21, 29, and 31.

SUMMARY

In summary, Appellant respectfully requests reversal of the March 31, 2005 Office Action rejection of claims 1-31.

Respectfully submitted,

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arnold P. Nerenberg
Filed: 07/23/2003
Serial No.: 10/625,305
Group Art Unit: 1651
Examiner: Ware, Deborah K.
Docket No.: NERE-3692

Title: **COMPOSITION FOR MITIGATING A PERNICIOUS THROMBOTIC EVENT**

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPENDIX A - CLAIMS ON APPEAL

1. A composition, comprising: aspirin, magnesium, and nattokinase, and either niacin or nitroglycerine, said composition having a structural form that is suitable for being introduced into a body of a person.

2. The composition of claim 1, wherein the composition is adapted to be introduced into the body of the person for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person.

3. The composition of claim 2, wherein the pernicious thrombotic event in the person is a heart attack or stroke in the person.

4. The composition of claim 1, wherein the aspirin, magnesium, nattokinase, and niacin or nitroglycerine each have a therapeutically effective amount for mitigating adverse effects of an imminent or actually-occurring pernicious thrombotic event in the person.

5. The composition of claim 4, wherein the pernicious thrombotic event in the person is a heart attack or stroke in the person.

6. The composition of claim 1, wherein the structural form is a chewable form, and wherein the chewable form is adapted to being introduced into the mouth of the person.

7. The composition of claim 6, wherein the chewable form comprises a wafer or a chewable tablet.

8. The composition of claim 6, wherein the structural form is a dissolvable form, and wherein the dissolvable form is adapted to being introduced into the mouth of the person.

9. The composition of claim 1, wherein the structural form is a liquid form.

10. The composition of claim 1, wherein the structural form is a spray form, and wherein the spray form is adapted to being introduced into the nasal cavity of the person.

11. The composition of claim 1, wherein the structural form is a suppository form, and wherein the suppository form is adapted to being introduced into the anal cavity of the person.

12. The composition of claim 1, wherein the composition comprises niacin.

13. The composition of claim 12, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, and wherein the niacin has an amount in a range of 500 to 3000 mg.

14. The composition of claim 12, further comprising L-carnitine.

15. The composition of claim 14, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the niacin has an amount in a range of 500 to 3000 mg, and wherein the L-carnitine has an amount in a range of 2000 to 9000 mg.

16. The composition of claim 14, further comprising alpha lipoic acid.

17. The composition of claim 16, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the niacin has an amount in a range of 500 to 3000 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, and wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg.

18. The composition of claim 16, further comprising L-arginine.

19. The composition of claim 18, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the niacin has an amount in a range of 500 to 3000 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg, and wherein the L-arginine has an amount in a range of 2000 to 12000 mg.

20. The composition of claim 18, further comprising coenzyme Q10.

21. The composition of claim 20, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the niacin has an amount in a range of 500 to 3000 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg, wherein the L-arginine has an amount in a range of 2000 to 12000 mg, and wherein the coenzyme Q10 has an amount in a range of 300 to 6000 mg.

22. The composition of claim 1, wherein the composition comprises nitroglycerine.

23. The composition of claim 22, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, and wherein the nitroglycerine has an

amount in a range of 0.4 to 2.5 mg.

24. The composition of claim 22, further comprising L-carnitine.

25. The composition of claim 24, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the nitroglycerine has an amount in a range of 0.4 to 2.5 mg, and wherein the L-carnitine has an amount in a range of 2000 to 9000 mg.

26. The composition of claim 24, further comprising alpha lipoic acid.

27. The composition of claim 26, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the nitroglycerine has an amount in a range of 0.4 to 2.5 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, and wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg.

28. The composition of claim 26, further comprising L-arginine.

29. The composition of claim 28, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the

nattokinase has an amount in a range of 150 to 3000 mg, wherein the nitroglycerine has an amount in a range of 0.4 to 2.5 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg, and wherein the L-arginine has an amount in a range of 2000 to 12000 mg.

30. The composition of claim 28, further comprising coenzyme Q10.

31. The composition of claim 30, wherein the aspirin has an amount in a range of 650 to 975 mg, wherein the magnesium has an amount in a range of 300 to 3000 mg, wherein the nattokinase has an amount in a range of 150 to 3000 mg, wherein the nitroglycerine has an amount in a range of 0.4 to 2.5 mg, wherein the L-carnitine has an amount in a range of 2000 to 9000 mg, wherein the alpha lipoic acid has an amount in a range of 200 to 10000 mg, and wherein the L-arginine has an amount in a range of 2000 to 12000 mg, and wherein the coenzyme Q10 has an amount in a range of 300 to 6000 mg.

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APPENDIX B - EVIDENCE

There is no evidence entered by the Examiner and relied upon by Appellants in this appeal.

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APPENDIX C - RELATED PROCEEDINGS

There are no proceedings identified in the "Related Appeals and Interferences" section.